Stanford Medical School
Blood Center

5726 '02 JUL -2 A9:13

July 1, 2002

Dockets Management Branch (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

Re: Docket No. 02D-0096
Draft Guidance: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV

To the Docket:

This draft guidance document proposes to require implementation of donor screening tests for HIV and HCV nucleic acid within 6 months of publication of the final guidance. However, the document gives NO guidance on a number of crucial issues that blood collection agencies will be faced with when they identify a donor with a positive test. These issues include:

1. Disposition of products from units that test reactive on a nucleic acid test at the individual level.
2. Disposition of products from PRIOR collections from donors that currently test reactive on a nucleic acid test.
3. Notification of recipients of products from PRIOR collections from donors that currently test reactive on a nucleic acid test.
4. Deferral of donors that test reactive on a nucleic acid test. Eligibility of such donors for re-entry.
5. Clarification as to whether nucleic acid testing is required for autologous donations.

The IND protocols for the clinical trials of nucleic acid testing address many of these issues. Under IND, blood collection agencies are prohibited to release units that test positive, and required to defer donors that tested positive and to retrieve products from prior donations. However, once the test becomes licensed, blood collection agencies are no longer bound by the requirements of the IND. Blood collection agencies that did not participate in one of the clinical trials have never received guidance on these issues. It is absolutely essential that blood collection agencies have clear instructions on the above donor and product management issues at the time that they implement nucleic acid testing.

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Blood collection agencies cannot be expected to implement a donor-screening test in the absence of instructions related to donor and product management in the event of a positive test. These issues are somewhat complex. However, most have been discussed thoroughly at Blood Products Advisory Committee meetings. Therefore, the agency should have sufficient knowledge to develop a draft guidance document related to donor and product disposition issues. The agency should issue a draft guidance on donor and product management as soon as possible so that comments may be received and these instructions finalized. The final guidance document requiring nucleic acid tests should not be issued until final guidance on donor and product

management can be included. In the absence of final guidance related to donor and product management, it is actually safer from a public health perspective to continue testing under IND, because the IND protocols do include donor and product management instructions that protect public safety.

Sincerely,

Susan A Galel

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SPL13

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